K023906

Pathway™

"Restoring function with innovative technology"

FEB 19 2003

PREMARKET NOTIFICATION [510(k)] SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Date Prepared: November 4, 2002

Applicant: The Prometheus Group
Address: 1 Washington St
Suite 303
Dover NH 03820

Contact: Heather Magoon
Electronics Engineer
Tel.: 603.749.0733
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Pathway™

"Restoring function with innovative technology"

Device Name:
Trade Name: Pathway CTS2000 Pelvic Floor Training System
Common Name: Non-implanted Electrical Continence Device
Classification Name: CLASS II, 78KPI (876.5320)

Predicate Device(s):
Trade Name: Pathway CTS2000 Pelvic Floor Training System K001515
Manufacturer: The Prometheus Group

Trade Name: Hollister InCare PRS Pelvic Floor Therapy System K974048
Manufacturer: Hollister, Inc.

Description of Device:

The Pathway CTS2000 Pelvic Floor Training System provides electromyographic or pressure biofeedback from pelvic musculature as well as provides electrical stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of urinary incontinence.

The Pathway CTS 2000 uses Pathway Perineometer Sensors which are single-user sensors, and inserts the sensor into the vagina or rectum while using the Pathway CTS 2000 Pelvic Floor Training System to monitor the muscle activity during contraction and relaxation of the pelvic floor muscles. The patient can also use the Pathway CTS 2000 Pelvic Floor Training System to electrically stimulate the pelvic floor muscles to assist the contraction. The aim is to improve the strength and control of the pelvic floor muscles.

The purpose of this premarket notification submission is to include additional electrical stimulation treatment frequencies of 100 and 200 Hz to the existing Pathway CTS2000 Pelvic Floor Therapy System, K001515.

Intended Use:

Indications for Use:
Urinary Incontinence; Stress, Urge and Mixed Incontinence
Neuromuscular Reeducation
Fecal Incontinence; EMG USE ONLY

The Prometheus Group ™
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Technical Characteristics Comparison:

	PROPOSED DEVICE	Pathway CTS2000 K001515	InCare PRS K974048
Intended Use	Treatment of Urinary Incontinence	Treatment of Urinary Incontinence	Treatment of Urinary Incontinence
Stimulator Output	0-100 mA	0-100 mA	0-30 V
Waveform	Asymmetrical Balanced Pulsed Current	Asymmetrical Balanced Pulsed Current	Square, Symmetrical, Balanced, Biphasic
Charge/pulse at 500 ohms	28uC	28uC	60uC
Frequency	12.5, 50, 100, 200 Hz	12.5, 50 Hz	12.5, 20, 50, 100, 200 Hz
Peak pulse intensity	100 mA	100 mA	30V
Pulse width	.3 ms fixed	.3 ms fixed	.3 ms, 1 ms
Ramps	2 sec on ramp, one sec off ramp	2 sec on ramp, one sec off ramp	On ramp: 20%, 40%, 60%, 80%, 100% of "On" time, no off ramp
Duty Cycle	On (sec): 1-80 Off (sec): 0-80	On (sec): 1-80 Off (sec): 0-80	On (sec): 1-80 Off (sec): 0-80
Session Duration (min)	0-30	0-30	0-30
Programmable features	None by Patient; Frequency, Duty cycle, Session Length by physician	None by Patient; Frequency, Duty cycle, Session Length by physician	None by patient; Pulse width, Frequency, Duty cycle, Session Length by physician
Vaginal EMG/Stim Probe Used	Pathway Vaginal EMG/Stimulation Sensor K993976	Pathway Vaginal EMG/Stimulation Sensor K993976	InCare Vaginal EMG/Stim Probe K891773
Anal EMG/Stim Probe Used	Pathway Anal EMG/Stimulation Sensor K993976	Pathway Anal EMG/Stimulation Sensor K993976	InCare Anal EMG/Stim Probe K930530
Vaginal EMG/Stim probe electrode surface area:	2.31 cm^2	2.31 cm^2	7.98 cm^2
Anal EMG/Stim probe Electrode surface area:	2.12 cm^2	2.12 cm^2	1.99 cm^2
Current Density (full output)	Pathway Vaginal EMG/Stim Sensor: .043 A/cm^2 Pathway Anal EMG/Stim Sensor: .047 A/cm^2 (Max. Instantaneous)	Pathway Vaginal EMG/Stim Sensor: .043 A/cm^2 Pathway Anal EMG/Stim Sensor: .047 A/cm^2 (Max. Instantaneous)	Probe 9595 - .003 A/cm^2 Probe 9596 - .018A/cm^2 (1ms pulse, 100Hz, 500ohm)
Power Density (full output @ 500 ohms)	Pathway Vaginal EMG/Stim Sensor: 7.79 mW/cm^2 Pathway Anal EMG/Stim Sensor: 8.49 mW/cm^2 (.3mS pulse, 200Hz)	Pathway Vaginal EMG/Stim Sensor: .487 mW/cm^2 Pathway Anal EMG/Stim Sensor: .531 mW/cm^2 (.3mS pulse, 50Hz)	Probe 9595 - .047 W/cm^2 Probe 9596 - .239 W/cm^2 (1ms pulse, 100Hz)
EMG Ranges	0-5, 0-30, 0-100, 0-1000 uV Ranges	0-5, 0-30, 0-100, 0-1000 uV Ranges	0-5, 0-10, 0-25, 0-100, 0-250, 0-500 uV Ranges
EMG Bandwidth	20-500Hz	20-500Hz	100-500 Hz
EMG Signal Processing	Root Mean Square (RMS)	Root Mean Square (RMS)	Root Mean Square (RMS)
EMG Detection	Bipolar	Bipolar	Bipolar
Vaginal Pressure Probe Used	Pathway Vaginal Pressure Sensor manufactured by DesChutes Medical K934552.	Pathway Vaginal Pressure Sensor manufactured by DesChutes Medical K934552	InCare Vaginal Pressure Probe K891774
Anal Pressure Probe Used	Pathway Anal Pressure Sensor manufactured by DesChutes Medical K934552.	Pathway Anal Pressure Sensor manufactured by DesChutes Medical K934552	InCare Anal Pressure Probe K891774
Work Period (sec)	1-80 seconds	1-80 seconds	1-80 seconds
Rest Period (sec)	0-80 seconds	0-80 seconds	0-80 seconds
Session Duration (min)	1-60 minutes	1-60 minutes	1-60 minutes

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Non-Clinical Performance Data:

The bench tests conducted provide sufficient data to establish substantial equivalency to the original device Pathway CTS2000 Pelvic Floor Training System K001515 and substantial equivalency to the predicate device InCare PRS Pelvic Floor Training System K974048.

Biocompatibility:

The Pathway Vaginal EMG/Stimulation Perineometer Sensor, the Pathway Anal EMG/Stimulation Perineometer Sensor, The Pathway Vaginal Pressure Perineometer Sensor, and the Pathway Anal Pressure Perineometer Sensor have been laboratory tested for the safety of the materials. The Pathway Perineometer Sensors were found to be safe under the standards required for each test.

Conclusion:

The Pathway CTS 2000 Pelvic Floor Training System is safe and effective for its intended use. The Pathway CTS 2000 Pelvic Floor Training System is substantially equivalent to the predicate device and to the existing Pathway CTS2000 Pelvic Floor Training System K001515.

END OF 510(k) SUMMARY

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Ms. Heather Magoon
Electrical Engineer
The Prometheus Group
1 Washington Street, Suite 303
DOVER NH 03820

Re: K023906
Trade/Device Name: Pathway CTS2000 Pelvic Floor Training System
Regulation Number: 21 CFR §876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: 78 KPI
Dated: November 15, 2002
Received: November 22, 2002

Dear Ms. Magoon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 2 - STATEMENT OF INDICATIONS FOR USE

2.1 PATHWAY CTS2000 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K023906
Device Name: Pathway CTS 2000 Pelvic Floor Training System

Indications for Use:

Indications For Use

- **Urinary Incontinence: Stress, Urge and Mixed Incontinence**
- **Neuromuscular Reeducation**
- **Fecal Incontinence: EMG USE ONLY**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-the-Counter Use: _____

(Per 21 CFR 801.109)

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023906